



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances Registration: Mylan Pharmaceuticals, Inc.

[Docket No. DEA-392]

ACTION: Notice of registration.

SUMMARY: Mylan Pharmaceuticals, Inc. applied to be registered as an importer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Mylan Pharmaceuticals, Inc. registration as an importer of those controlled substances.

SUPPLEMENTARY INFORMATION:

By notice dated December 4, 2015, and published in the *Federal Register* on December 10, 2015, 80 FR 76709, Mylan Pharmaceuticals, Inc., 3711 Collins Ferry Road, Morgantown, West Virginia 26505 applied to be registered as an importer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Mylan Pharmaceuticals, Inc. to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of the following basic classes of controlled substances:

<u>Controlled Substance</u>	<u>Schedule</u>
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Pentobarbital (2270)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Morphine (9300)	II
Oxymorphone (9652)	II
Remifentanyl (9739)	II
Fentanyl (9801)	II

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company's own domestically-manufactured FDF. This analysis is required to allow the company to export domestically-manufactured FDF to foreign markets.

Dated: March 28, 2016

Louis J. Milione,
Deputy Assistant Administrator.